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VERIFICATION OF TRANSLATION

I, Melissa Stanford, a translator with Chillson Translating Service, 3530 Chas Drive, Hampstead, Maryland, 21074, hereby declare as follows:

That I am familiar with the German and English languages;

That I am capable of translating from German to English;

That the translation attached hereto is a true and accurate translation of German Application 197 18 342.5 titled, "Process for Electrochemical Coating of Stents with Radioactive Isotopes" filed with the German Patent Office on April 30, 1997;

That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true;

And further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any registration resulting therefrom.

By Melissa Stanford

Executed this 11 day of Oct 1999.

Witness Anne Chills

Translator's Notes:

The heading of Example 4 cites "eines Palmaz-Stents-Stents [a Palmaz-stent stent]," which is presumably a typographical error for "eines Palmaz-Schatz Stents [a Palmaz-Schatz stent]." The heading was translated literally, however (English page 11, line 9).

In Examples 5-11, it appears that in the first half of the sentence, a verb was forgotten: specifically, "a [Strecker or Z or nitinol] stent is ___ in an electrolysis cell," where the missing word (represented by the underline in this Note) probably should be "placed." A literal translation is rendered here, however, namely "a [Strecker or Z or nitinol] stent...is in an electrolysis cell...."

FEDERAL REPUBLIC OF GERMANY

Certificate

The SCHERING AKTIENGESELLSCHAFT, Berlin/Germany filed a patent application under the designation

"Process for Electrochemical Coating of Stents
with Radioactive Isotopes"

with the German Patent Office on April 30, 1997.

The attached copies are a true and accurate rendition of the original document of this patent application.

In the German Patent Office the application has provisionally received the symbols A 61 L, A 61 M and A 61 F of the International Patent Classification.

[Seal]

Munich, July 15, 1998

For the Director of the German Patent Office

/s/

Agurks

File No.: 197 18 342.5

**Process for Electrochemical Coating of Stents
with Radioactive Isotopes**

The invention relates to a process for the production of radioactive stents by electrochemical coating by means of galvanization or cementation.

Prior Art

Radioactive stents are prior art (EP 0433011, WO 94/26205, US 5176617). Stents are self-expanding endoprotheses that make it possible to keep open duct-like structures in the bodies of humans or animals (e.g., vascular, esophageal, tracheal and bile duct stents). They are used as palliative measures in the case of stenoses by obstruction (e.g.: arteriosclerosis) or external pressure (e.g., in the case of tumors). Radioactive stents are used, for example, after vascular-surgery interventions (e.g., balloon angioplasty) for restenosis prophylaxis. Such radioactive stents can be produced, for example, by activation of a non-radioactive stent using irradiation with protons or deuterons from a cyclotron (WO 94/26205).

There is now the problem that, on the one hand, generally no cyclotron is available at the site of the use of the stent to undertake an activation of the stent, and, on the other hand, the

activated stent cannot be transported in any arbitrary way due to the sometimes short half-life of the activated isotope and for reasons of protection against radiation.

The object of this invention is therefore to make available a process for the production of radioactive stents, which makes it possible to coat with the suitable radioactive isotope the non-radioactive stent that is selected by the attending physician for this medical problem.

This object is achieved by the process that is described below, as it is characterized in the claims.

Description of the Invention

The above-described object is achieved according to the invention by an electrochemical deposition of the radioactive isotope on the stent.

To this end, the selected stent is immersed in a solution that contains the radioactive isotope. The radioactive isotope is then chemically deposited. Depending on the selected material of the stent, on the one hand, and the radioactive isotope that is to be deposited, on the other hand, two possible types of deposition are considered:

- 1) **Electroplating (external electrolysis)**

During electroplating, the dissolved radioactive isotope is deposited reductively by applying electrical direct current to the stent that is connected as a cathode.

In this way, for example, copper, rhenium, silver or indium can be deposited on the metal stents (e.g., steel, nitinol).

2) Cementation (internal electrolysis)

During cementation, the dissolved noble radioactive isotope is deposited on the non-noble stent material without applying electrical current due to the position of the materials in the voltage sequence of the metals. In this way, for example, gold, silver or copper can be deposited on metal stents (e.g., steel, nitinol).

Detailed Description of the Invention

For the coating of metal stents, two electrochemical processes have proven especially suitable: electroplating (electrolytic coating) and cementation (internal electrolysis). The process with the broader range of application is the electroplating, since it also makes possible the coating with an electrochemically more negative material than that of the stent. The coating also makes possible chemical reactions -- for example reductive processes.

From the user-friendly operation, it can be seen that the cementation is the better process: the stent is added to the solution of an electrochemically more positive element, and the coating is carried out without a parasitic current.

By suitable cell shape, the excess coating material can be kept small. The necessary stirring can be done by a magnetic stirrer or by moving the stent manually. Since only small

amounts of substance are applied in this process, manual stirring is reasonable. The same also holds true for reactions at elevated temperature: because of the short time available, thermostating is not necessary; preheating is all that is required.

The coating of cells (Figs. 1, 2) can be carried out with hypodermic syringes or -- in the case of larger stents -- with the aid of metering pumps. With these larger cells, it is useful to separate used electrolyte solution (active) and washing liquid (inactive) to keep the volume of active liquid small.

In the cells that are described in Figs. 1, 2, the stent is placed with its carrier in the vessel, whereby an elevated location with a trough provides for the positioning. In the case of a galvanization cell, this trough contains a Pt sheet as a contact for the stent that is connected as a cathode. A Pt network is located on the cell wall as an anode. By using one of the ring-shaped sheets that is connected in an electrically conducting manner with the anode and that is made of another metal, the operation can also be done with tin, zinc or copper anodes.

The use of the stent with its carrier has the advantage that the inside of the stent is shielded, and thus no coating is carried out there. The coating is carried out only at the locations that are directed against the vessel.

Since a restenosis is suppressed by the coating, an electropolishing of the crude stent may be omitted -- especially in the case of high-grade steel.

Some Possible Types of Electrochemical Labeling of Stents

The labeling can be performed according to different processes.

1. Galvanostatic Deposition

For this purpose, a battery (1.5 - 6 V) that is connected with a variable resistor and 2 electrode terminals is sufficient. The metal that is to be coated is connected as a cathode. As an anode, a noble metal, preferably platinum, should be used. The electrolysis period is 20 seconds to 30 minutes. The operation is performed at temperatures of 0°-80°C, but preferably at room temperature.

Cu:

(e.g., Cu-67, β and γ Str., $t_h = 61.9$ h)

from pyrophosphate baths of the composition below:

Cu^{2+}	:	20-40 g
$(\text{P}_2\text{O}_7)^{4-}$:	15-250 g
NO_3^-	:	5-10 g
NH_3	:	1-3 g
$(\text{HPO}_4)^{2-}$:	< 110 g
pH	:	8-9
I	:	1-8 A/dm ²

from CuCN baths at pH 12.2-12.8

from acid baths of

- sulfate-oxalate-boric acid
- CuCl/Na-thiosulfate
- fluoroborate, fluoro-silicate, formate
- Cu^{II}/gluconate, lactate, maleate, tartrate

$$I = 1-2.5 \text{ A/dm}^2$$

$$U = 0.2-6 \text{ V}$$

$$\text{pH} = 1.2$$

Au:

(Au-199, $t_k = 3 \text{ d}$, β and γ Str.)

from cyanidic baths with the addition of phosphate and citrate at pH 5-12, thiourea, $\text{NH}_4\text{ClKAuCN}_2$ at pH 6.5-7

$$I = 0.1-0.6 \text{ A/dm}^2$$

In:

from cyanidic baths at pH = 0-1

from fluoroborate baths with the addition of tartaric acid at pH 1

$\text{In}_2(\text{SO}_4)_3$ pH 2-3/or sulfamate and tartrate

Re:

from perrhenate Re-186

citrate + H_2SO_4 , pH 1-5

$$I = 1-15 \text{ A/dm}^2$$

Ni:

from NiSO_4 /boric acid, acetate, fluoroborate, sulfamate,

$$\text{pH} = 1-5$$

$$I = 2-30 \text{ A/dm}^2$$

Pt, Rh, Pd, Ru:

(Pt¹⁹⁷, $t_{1/2} = \beta$ Str.)

$I = 1-4 \text{ A/dm}^2$

Ru from $(\text{NH}_3)_4(\text{Ru}_2\text{NC}_{18}(\text{H}_2\text{O})_2)$ or sulfamate

Rh from sulfate, phosphate, H_2SO_4

pH = 1-2

Pd from $\text{Pd}(\text{NH}_3)_4\text{Br}_2$, ETDA,

Pt from NH_4NO_2 , NH_3

sulfamate

$\text{H}_2\text{Pt}(\text{NO}_2)_2\text{SO}_4$, H_2SO_4

$\text{K}_2\text{Pt}(\text{OH})_6$, KOH · ethylamine

H_2PtCl_6 , HCl

Ag:

(Ag-110, $t_{1/2} = 250\text{d}$)

from cyanidic baths, KOH

Zero-current deposition/chemical reduction

$\text{M}^{2+} + 2\text{e}^-$ (from the reducing agent) - catalytic surface $\rightarrow \text{M}^0$

Hypophosphite: (with Ni)

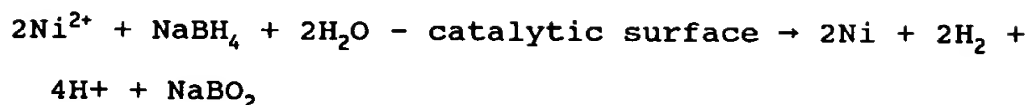
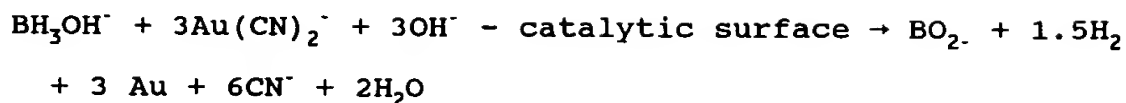
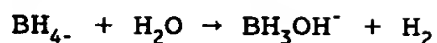
$\text{H}_2\text{PO}_2^- + \text{H}_2\text{O}$ - catalytic surface $\rightarrow \text{HPO}_3^{2-} + 2\text{H}^+ + \text{H}^-$

$2\text{H}^- + \text{Ni}^{2+} \rightarrow \text{Ni} + \text{H}_2$

Addition of citrate, acetate, fluoride, succinate, lactate,
propionate

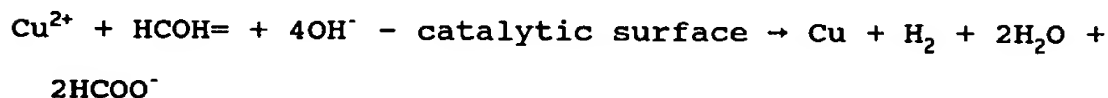
pH = 4-11

NaBH₄: (with Au)



Additions of dimethylammonium borane, boric acid, citric acid, malonic acid, glycine, pyrophosphate, malic acid, pH = 4-10

Formaldehyde: (with Cu)

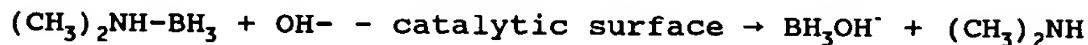


with the addition of NaKtartrate, NaOH

Hydrazine: (with Pt)

Pd with the addition of NH₄OH, EDTA,

Dimethylaminoborane (CH₃)₂NH-BH₃ (with Au, Ag)



Au and Ag from cyanidic baths

The stents can also be coated with two or more different isotopes. In particular, it is possible to apply short-lived and

long-lived isotopes together on a stent (for example, ^{55}Co with ^{55}Fe or ^{99}Mo with ^{57}Co).

The operations that are necessary for implementing the above processes that are described in principle are known to one skilled in the art. Special embodiments are described in detail in the examples.

The stents according to the invention achieve the above-described object. Stents can be radiolabeled easily by the disclosed processes and metered precisely. The stents according to the invention are readily physiologically compatible. As it was possible to show in the animal model, the restenosis is significantly inhibited after balloon denudation by implantation of the stent according to the invention.

The special advantage of the stent according to the invention is that the physician can select on the spot a (non-radioactive) stent according to his needs and can then activate the selected stent by the described process. The few substances and solutions that are required for this purpose can be supplied prepared accordingly, so that the corresponding physician need only immerse the uncoated stent in the individual solutions in the specific sequence. The invention thus also relates to those substances, solutions and preparations (kits) that are prepared for the processes according to the invention.

Embodiments:

The following examples are to explain the subject of the invention, without intending that it be limited to these examples.

Example 1**Labeling of a Strecker Stent with Cu-67**

A Strecker stent (93 mg) is fixed in an electrolysis cell as described in Fig. 1. Then, the cell is made up with a 5% aqueous hydrochloric acid solution, and a Cu-67 solution is added (starting activity 47.4 MBq). Then, a voltage of 2 V is applied. Electrolysis is done for 5 minutes at room temperature. The radioactive solution is drained off via a valve, and the stent is washed four times with physiological common salt solution. A Strecker stent whose surface is labeled in this way contains a radioactivity of 1.56 MBq and can be used directly as an implant.

Example 2**Labeling of a Nitinol Stent with Cu-67**

A nitinol stent (about 500 mg) was labeled analogously as described in Example 101. Electrolysis was done for 10 minutes at 1.5 V, however. The stent showed a radioactivity of 3.21 MBq.

Example 3**Labeling of a Nitinol Stent with Re-186**

A nitinol stent (about 1000 mg) is fixed in an electrolysis cell as described in Fig. 1. Then, phosphate buffer (0.01 mol/l,

pH 5) is added. Then, an Re-186 solution (starting activity 51.4 MBq) is added, and a voltage of 2.5 V is applied. Electrolysis is done for 10 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 2.44 MBq.

Example 4

Labeling of a Palmaz-Stent Stent (316 Stainless Steel) with Re-186

A Palmaz stent (about 200 mg) is fixed in an electrolysis cell (Fig. 1), and a solution that consists of 5% aqueous nitric acid, in which 150 mg of sodium chloride/ml is dissolved, is added. An Re-186 solution (starting activity: 37.4 MBq) is added, and a voltage of 2.3 V is applied. Electrolysis is done for 5 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 1.98 MBq.

Example 5

Labeling of a Strecker Stent with Au-199

A Strecker stent (about 150 mg) is in an electrolysis cell (Fig. 1), and a solution of 7.5% aqueous hydrochloric acid is added. Then, an Au-199 solution (starting activity: 45.2 Mbq) is added, and a voltage of 1.5 V is applied. Electrolysis is done for 5 minutes at room temperature. The radioactive solution

is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 2.13 MBq.

Example 6

Labeling of a Strecker Stent with Au-199

A Strecker stent (about 350 mg) is in an electrolysis cell (Fig. 1), and a solution that consists of 2.5% aqueous hydrochloric acid, in which 100 mg of tetramethylammonium chloride/ml is dissolved, is added. Then, an Au-199 solution (starting activity: 55.6 MBq) is added, and a voltage of 1.2 V is applied. Electrolysis is done for 4 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 1.81 MBq.

Example 7

Labeling of a Z-Stent (304 Stainless Steel) with Au-199

A Z-stent (about 250 mg) is in an electrolysis cell (Fig. 1), and a solution of 2.5% aqueous nitric acid, in which 100 mg of tetramethylammonium chloride/ml is dissolved, is added. Then, an Au-199 solution (starting activity: 38.6 MBq) is added, and a voltage of 1.2 V is applied. Electrolysis is done for 3 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 1.13 MBq.

Example 8

Labeling of a Z-Stent (304 Stainless Steel) with Ag-110

A Z-stent (about 250 mg) is in an electrolysis cell (Fig. 1), and a solution of 5% aqueous nitric acid, in which 100 mg of tetramethylammonium nitrate/ml is dissolved, is added. Then, an Ag-110 solution (starting activity: 56.8 MBq) is added, and a voltage of 1.5 V is applied. Electrolysis is done for 2 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with physiological common salt solution. The stent showed a radioactivity of 1.54 MBq.

Example 9

Labeling of a Nitinol Stent (304 Stainless Steel) with Ag-110

A nitinol stent (about 1500 mg) is in an electrolysis cell (Fig. 1), and a solution that consists of 7.5% aqueous nitric acid, in which 150 mg of tetramethylammonium nitrate/ml is dissolved, is added. Then, an Ag-110 solution (starting activity: 39.4 MBq) is added, and a voltage of 1.4 V is applied. Electrolysis is done for 10 minutes at room temperature. The radioactive solution is removed, and the stent is washed four times with water and twice with physiological common salt solution. The stent showed a radioactivity of 1.78 MBq.

Example 10

Labeling of a Nitinol Stent with In-111

A nitinol stent (about 1500 mg) is in an electrolysis cell (Fig. 1), and a solution of 5% aqueous citric acid, in which 150

mg of tetramethylammonium chloride/ml is dissolved, is added. Then, an In-111 solution (starting activity: 51.3 MBq) is added, and a voltage of 3.5 V is applied. Electrolysis is done for 7 minutes at room temperature. The radioactive solution is removed, and the stent is washed twice with water and twice with physiological common salt solution. The stent showed a radioactivity of 1.45 MBq.

Example 11

Labeling of a Z-Stent with In-111

A Z-stent (about 500 mg) is in an electrolysis cell (Fig. 1), and a solution that consists of 5% aqueous citric acid, in which 150 mg of tetramethylammonium chloride/ml is dissolved, is added. Then, an In-111 solution (starting activity: 36.9 MBq) is added, and a voltage of 3.8 V is applied. Electrolysis is done for 12 minutes at room temperature. The radioactive solution is removed, and the stent is washed twice with water and twice with physiological common salt solution. The stent showed a radioactivity of 1.77 MBq.

Example 12

Labeling of a Strecker Stent with Au-199

In a cementation vessel (Fig. 2b), a Strecker stent (about 93 mg) is mixed with an aqueous hydrochloric acid solution (pH 3). Au-199 chloride solution (starting activity: 32.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt

solution and can be used directly for implantation. The stent showed a radioactivity of 1.22 MBq.

Example 13

Labeling of a Strecker Stent with Ag-110

In a cementation vessel (Fig. 2a), a Strecker stent (about 496 mg) is mixed with an aqueous nitric acid solution (pH 4). Ag-110 nitrate solution (starting activity: 37.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with dilute nitric acid (pH 3) and twice with water, and it can be used directly for implantation. The stent showed a radioactivity of 1.02 MBq.

Example 14

Labeling of a Z-Stent with Au-199

In a cementation vessel (Fig. 2a), a Z-stent (about 987 mg) is mixed with an aqueous hydrochloric acid solution (pH 3). Au-199 chloride solution (starting activity: 41.5 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 1.13 MBq.

Example 15

Labeling of a Nitinol Stent with Au-199

In a cementation vessel (Fig. 2b), a nitinol stent (about 488 mg) is mixed with an aqueous hydrochloric acid solution (pH

3). Au-199 chloride solution (starting activity: 39.7 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 0.98 MBq.

Example 16

Labeling of a Strecker Stent with Re-186

A Strecker stent is brought into an electrolysis cell (Fig. 1), and a solution of sulfuric acid zinc sulfate solution (50 mg/ml, pH 5) is added. After a zinc anode is introduced, electrolysis is done at a voltage of 1.5 V for 10 minutes. The galvanized stent is washed four times with water. In a cementation vessel (Fig. 2a), the above-described stent is mixed with an aqueous citric acid solution (pH 5). Re-186 solution (starting activity: 41.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 1.31 MBq.

Example 17

Labeling of a Z-Stent (304 Stainless Steel) with Re-186

A Strecker stent is brought into an electrolysis cell (Fig. 1), and a solution of hydrochloric acid tin(II) chloride solution (50 mg/ml, pH 5) is added. After a tin anode is introduced, electrolysis is done at a voltage of 3 V for 5 minutes. The stent that is thus tinned is washed four times with water. In a

cementation vessel (Fig. 2a), the above-described stent is mixed with an aqueous citric acid solution (pH 5). Re-186 solution (starting activity: 37.7 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 1.44 MBq.

Example 18

Labeling of a Nitinol Stent with Cu-67

In a cementation vessel (Fig. 2b), a nitinol stent (about 488 mg) is mixed with an aqueous hydrochloric acid solution (pH 3). Cu-67 sulfate solution (starting activity: 24.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 1.55 MBq.

Example 19

Labeling of a Palmaz Stent (316 Stainless Steel) with Cu-67

In a cementation vessel (Fig. 2a), a Palmaz stent (about 977 mg) is mixed with an aqueous hydrochloric acid solution (pH 3). Cu-67 sulfate solution (starting activity: 24.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 0.88 MBq.

Example 20

Labeling of a Palmaz Stent (316 Stainless Steel) with Re-186

A Palmaz stent is brought into an electrolysis cell (Fig. 1), and a solution of hydrochloric acid tin(II) chloride solution (50 mg/ml, pH 5) is added. After a tin anode is introduced, electrolysis is done at a voltage of 3 V for 5 minutes. The thus tinned stent is washed four times with water. In a cementation vessel (Fig. 2b), the above-described stent is mixed with an aqueous citric acid solution (pH 5). Re-186 solution (starting activity: 34.5 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with physiological common salt solution and can be used directly for implantation. The stent showed a radioactivity of 1.98 MBq.

Example 21

Labeling of a Palmaz Stent (316 Stainless Steel) with Ag-110

In a cementation vessel (Fig. 2a), a Palmaz stent (about 977 mg) is mixed with an aqueous nitric acid solution (pH 4). Ag-110 sulfate solution (starting activity: 24.6 MBq) is added, and it is stirred for 10 minutes at room temperature. The stent is washed four times with water and can be used directly for implantation. The stent showed a radioactivity of 1.12 MBq.

Claims

1. Radioactive stents, characterized in that the radioactive isotope was deposited electrochemically on the surface of the stent.

2. Process for the production of radioactive stents, wherein a non-radioactive stent is immersed in a solution that contains the radioactive isotope in ionic form, and the isotope is then electrochemically deposited on the stent.

3. Process for the production of radioactive stents according to claim 1, wherein the isotope is deposited galvanically on the stent.

4. Process for the production of radioactive stents according to claim 1, wherein the isotope is deposited on the stent by cementation.

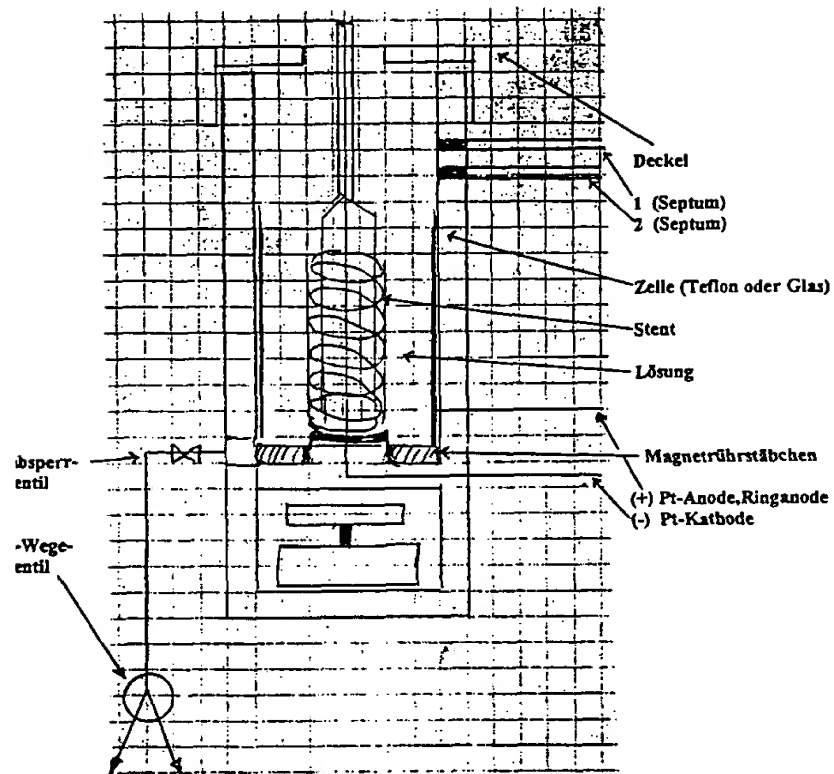
5. Process according to at least one of claims 2-4, wherein the radioactive isotope is an isotope of elements Ag, Au, Ba, Bi, C, Co, Cr, Cu, Fe, Ga, Gd, Hg, Ho, In, Ir, Lu, Mn, P, Pb, Pd, Pm, Re, Rh, Ru, Sb, Sc, Sm, Tb, Tc or Y.

**Process for Electrochemical Coating of Stents
with Radioactive Isotopes**

Abstract

The invention relates to a process for the production of radioactive stents by electrochemical coating by means of galvanization or cementation.

Galvanization Cell (Fig. 1)



**Addition of solutions: Hypodermic syringes or
metering pumps**

**When addition is done with hypodermic syringes:
Put septa in the cover.**

**If electrolysis is carried out at an elevated temperature,
the solution is preheated.**

- 1: Rinsing liquid**
- 2: Active solution**

[Key:]

Deckel = cover

Septum = septum

Zelle (Teflon oder Glas) = cell (teflon or glass)

Stent = stent

Lösung = solution

Absperrventil = shutoff valve

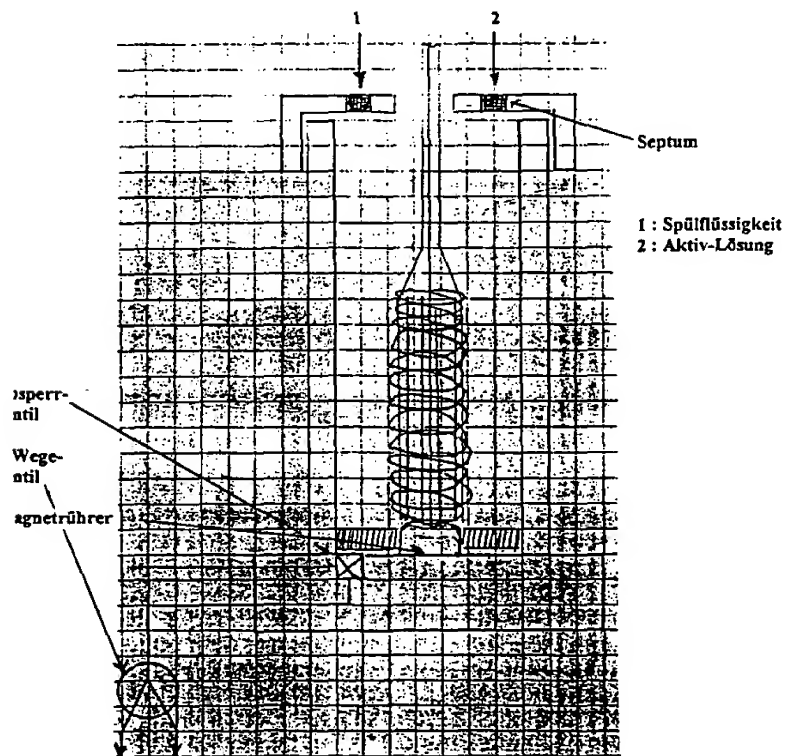
2-Wege-ventil = 2-way valve

Magnetrührstäbchen = magnetic stirring rod

(+) Pt-anode, Ringanode = (+) Pt-anode, ring anode

(-) Pt-Kathode = (-) Pt-cathode

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[Key to Fig. 2a:]

Deckel = cover

Zelle (Teflon oder Glas) = cell (teflon or glass)

Stent = stent

Magnetrührstäbchen = magnetic stirring rod

Magnetrühr = magnetic stirrer

Lösung = solution

[Key to Fig. 2b:]

Septum = septum

1. Spülflüssigkeit = rinsing liquid

2. Aktiv-Lösung = active solution

Absperrventil = shutoff valve

2-Wege-ventil = 2-way valve

Magnetrührer = magnetic stirrer